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CERTIFICATE UNDER 37 CFR 1.10

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By: *Linda McCormick*
Name: Linda McCormick

BOX PATENT APPLICATION

Assistant Commissioner for Patents
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Sir:

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.10.
- ☒ Utility Patent Application: Spec. 9 pgs; 21 claims; Abstract 1 pgs.:
- ☒ 1 sheets of drawings
- ☒ An unsigned Combined Declaration and Power of Attorney
- ☒ Return postcard
- ☒ **PAYMENT OF THE FILING FEE IS BEING DEFERRED.**

MERCHANT & GOULD P.C.

P.O. Box 2903, Minneapolis, MN 55402-0903

(612) 332-5300

By: *James R. Chiapetta*

Name: James R. Chiapetta

Reg. No. 39,634

Initials: JRC:jkc



23552

PATENT TRADEMARK OFFICE

DISTRACTING AND CURETTING INSTRUMENT

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Field of the Invention

The present invention is directed to surgical devices and procedures. In particular, the invention provides instruments for curetting, bone distracting and removing tissue from a surgical site. In one embodiment, the invention is particularly advantageous for removing disc material from an intervertebral disc space.

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Background of the Invention

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Surgical instruments and techniques are known for performing procedures at and around vertebral bodies, including the intervertebral disc space. Such techniques include, for example, intervertebral disc decompression, vertebral fusion, etc. Often times such procedures include removing some or all of the disc material between vertebrae. Many known systems for removing disc material require multiple instruments or multiple steps for cutting the material to be removed, curetting the surfaces surrounding the disc material and removing the cut or curetted material from the disc space. The need for multiple instruments or multiple steps reduces surgical efficiency and can increase the overall time spent performing the procedure.

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Accordingly, there is a continuing need for instrumentation and methods which reduce the time and steps needed to perform cutting, curetting and/or removal procedures in surgery. The present invention is directed to addressing this need.

Summary of the Invention

The present invention provides instrumentation and methods for cutting, curetting and/or removing material from a surgical site. The invention also provides for distracting vertebrae that are adjacent an intervertebral disc space.

5 In one embodiment, the invention provides a surgical instrument having a proximal end spaced apart from a distal end along a shaft having a longitudinal axis passing therethrough. At the proximal end, the instrument includes a handle for operating the device. At the distal end, the instrument includes a working head including a blade for cutting, a distracting dimension for distracting and, in some embodiments, a
10 collecting element to collect cut material and facilitate removal of the cut material from the surgical site.

In a typical embodiment the blade of the working head includes a leading and a trailing end and has a serpentinoid or "S" shaped configuration. A first cutting surface extends along a first edge from the leading end to the trailing end of the blade and a
15 second cutting surface extends from the leading end to the trailing end along a second edge of the blade. If present, the collecting element is arranged to overlie some or all of the serpentinoid configuration at the leading end of the head. In addition, the working head can have a height dimension, width dimension and a diagonal dimension such that the diagonal dimension is greater than the height dimension which is greater than the
20 width dimension.

In use, rotation of the working head of the instrument around a longitudinal axis in a first direction provides for cutting and/or curetting materials surrounding the blade. The cutting surfaces are configured and arranged in such a manner that when rotated in

an opposite direction the cutting edges are not oriented for cutting material surrounding the blade. In addition, when positioned in an intervertebral disc space having a disc height less than the diagonal dimension of the working head, rotation of the instrument provides for distraction of the vertebrae adjacent to the disc space when the diagonal dimension of the blade is oriented at or near parallel with the longitudinal axis of the spinal column. The instruments of the invention can be particularly advantageous for use in cutting and/or curetting material from an intervertebral disc space.

Brief Description of the Drawings

FIG. 1 is a side view of a preferred embodiment of a surgical instrument according to the invention;

FIG. 2 is a side view of the surgical instrument of FIG. 1 rotated 90 degrees around axis X-X;

FIG. 3 is a perspective view of the working end of the surgical instrument of

FIG. 1;

FIG. 4 is a transverse cross-section through line 4-4 of the surgical instrument of FIG. 1;

FIG. 5 is a distal end-on view of the surgical instrument of FIG. 1; and

FIG. 6 is a transverse cross-section through line 6-6 of the surgical instrument of

FIG. 1.

Detailed Description

The invention is directed to surgical instruments for cutting, curetting and/or removing material from a surgical site. The instruments include a proximal end and distal end spaced apart along a shaft. A longitudinal axis X-X passes through the

5 instruments from the proximal end to the distal end. A working head is present at the distal end and a handle for operating the instrument at the proximal end. A blade for cutting and curetting is located on the working head. The working head can also provide for distraction of vertebrae adjacent an intervertebral disc space. In some embodiments, the working head can also include a collecting element to facilitate removal of material
10 from the surgical site.

In a preferred embodiment, the working head of the instrument includes a width dimension which is less than a height dimension which is less than a diagonal dimension. According to this embodiment, when the instrument is rotated around the longitudinal axis such that the diagonal dimension is oriented parallel to the long axis of the vertebral
15 column, the vertebrae can be distracted and will be spaced apart from each other by a distance determined by the diagonal dimension of the working head.

Throughout the present description guidance may be provided through lists of examples. In each instance, the recited list serves only as a representative group. It is not meant, however, that the list is exclusive.

20 Unless otherwise stated, the terms "proximal" and "distal" are relative terms, the term "proximal" referring to a location nearest the operator of the disclosed instruments and the term "distal" referring to a location farthest from the operator. Thus, generally, when using an instrument of the invention for cutting and removing material from an

intervertebral disc space through an anterior approach, the instrument is advanced from the anterior surface of the vertebral body (proximal) towards the posterior surface (distal) of the vertebral body. Likewise, in a posterior approach, the instrument is advanced from the posterior surface "proximal" toward the anterior surface "distal" of the vertebral body.

- 5 Similar relative orientations also apply for lateral approaches to the vertebrae.

The "height" of the disc space is the dimension from the end plate of a superior vertebrae to the end plate of an inferior vertebrae adjacent to the disc space.

- The height, width and diagonal dimension of the working head of an instrument of the invention can vary. Kits will be available including multiple instruments of the invention each having incrementally sized height, width and diagonal dimensions suitable for use in a particular surgical area for a particular surgical procedure.
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Detailed Description of the Illustrated Embodiment

The invention will be described with reference to the accompanying drawings.

- 15 The illustrated embodiment and description are for exemplary purposes to facilitate comprehension of the invention and should not be construed to limit the scope of the invention.

- FIG. 1 is a side view of one embodiment of a surgical instrument 10 according to the invention. As illustrated, surgical instrument 10 has a proximal end 1 and a distal end 2 spaced along a longitudinal shaft 3. The proximal end 1 of surgical instrument 10 includes a handle 4 for rotating surgical instrument 10 around longitudinal axis X-X passing through shaft 3. At distal end 2, surgical instrument 10 includes a working head
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5 having a leading end 6 and trailing end 7. Leading end 6 includes a tapered leading surface 8 at the leading end 6 of working head 5.

FIG. 2 is a side view of the surgical instrument 10 of FIG. 1 rotated 90 degrees around axis X-X and FIG. 3 is a perspective view of working head 5. As illustrated in

5 FIG. 3, working head 5 includes a blade 9 having a first cutting edge 11 and a second cutting edge 12 extending substantially from leading end 6 to trailing end 7. However, blade 9 need not extend completely between leading end 6 and trailing end 7. Leading end 6 can also include a collecting element 15 having a tapered distal tip 16 facing away from the leading end 6 and an opposing collecting surface 17 facing toward the leading
10 end 6. In the illustrated embodiment, collecting surface 17 includes a first collecting surface 17a and a second collecting surface 17b. Although preferred, collecting element 15 does not need to be present in an instrument of the invention.

FIG. 4 is a transverse cross-section view through line 4-4 of FIG. 1. As illustrated in this view, blade 9 has a serpentine or "S" shaped configuration in cross-sectional view.

15 Thus, blade 9 includes a first face 21 having a first concave surface 22 and a first convex surface 23. Blade 9 also includes a second face 25 having a second concave surface 26 and a second convex surface 27. In the illustrated embodiment, first cutting edge 11 faces in the same direction as first concave surface 22 and second cutting edge 12 faces in the same direction as second concave surface 26. Blade 9 of working head 5 also has a
20 height dimension H, a width dimension W that is less than height dimension H and a diagonal dimension D that is greater than height dimension H.

As best shown in FIG. 4, first collecting surface 17a extends from first face 21 over a portion of a region defined by first concave surface 22 at the leading end 6 of

blade 9. A second collecting surface 17b extends from second face 25 over a portion of a region defined by second concave surface 26 also at the leading end 6 of blade 9. In preferred embodiments, cutting edge 11 protrudes radially beyond a peripheral edge 30 of collecting surface 17a. Likewise, in the illustrated embodiment, cutting edge 12
5 protrudes radially beyond a peripheral edge 31 of collecting surface 17b.

FIG. 5 is a distal end-on view of surgical instrument 10. In this view, it will be appreciated that the tapered distal tip 16 of collecting element 15 can include a distal apex 41 to facilitate passing instrument 10 between adjacent surfaces in a surgical field.

FIG. 6 is a transverse cross-section view through line 6-6 of surgical instrument 10
10 illustrating blade 9 in relation to shaft 10.

As shown in FIG. 3, working head 5 can also include an indicator arrangement 50 such as markings 51 to indicate the depth of penetration of instrument 10 into a surgical site. The indicator arrangement 50 can include one or more markings that are incrementally spaced (e.g., 1 mm increments) that extend partially or fully around the
15 working head.

Surgical instrument 10 provides for cutting, curetting and/or removing material cut or curetted from a surgical site. For exemplary purposes, use of surgical instrument 10 will be described with reference to an intervertebral disc space between adjacent vertebrae. However, it will be appreciated that other uses are within the scope of the
20 invention. According to the present example, known methods can be used to provide exposure to the intervertebral disc space. An incision can be made into the vertebral annulus and the distal tip 16 inserted through the incision into the nucleus of the disc space. Alternatively, the annulus may have been previously herniated providing an

access to the nucleus. It is also foreseen that the distal apex 41 of distal tip 16 can be forcefully inserted through an intact annulus into the nucleus without first making an incision into the annulus. The longitudinal axis of apex 41 can be passed through the annulus into the disc space in a plane substantially perpendicular to the long axis of the vertebral column.

It is foreseen that a blade 9 may have a diagonal dimension D or height dimension H sufficient to distract the vertebrae adjacent the disc space. Instrument 10 can be inserted into the disc space with height dimension H oriented parallel to the end plates of the vertebrae. Once passed into the intervertebral space, the instrument 10 can be rotated in the direction of arrow 35 around longitudinal axis X-X by turning handle 4. When rotating in this direction cutting edges 11 and 12 are oriented to cut material (such as the nucleus or vertebral end plates) that is contacted by cutting edges 11 and 12 as instrument 10 is rotated. In addition, if diagonal dimension D is greater than the height of the disc space, during rotation, after cutting edges 11 and 12 contact the end plates of the vertebrae, blade 9 can also cause the end plates to distract or be forced apart from one another as the diagonal dimension D becomes oriented parallel to the long axis of the spinal column. When rotated in a direction opposite to that shown by arrow 35, the rounded corners at the ends of diagonal dimension D can still provide distraction of the vertebrae when the diagonal dimension D is oriented parallel to the long axis of the spinal column, but cutting edges 11 and 12 will not be oriented for cutting.

Thus, rotation of instrument 10 in one direction provides for cutting or curetting material. During rotation, the material cut can be stored along first and second concave surfaces 22 and 26. Specifically, the cut or curetted material collects along concave

surfaces 22 and 26. If a collecting element 15 is present, removal of the cut material from the surgical site can be facilitated by collecting surfaces 17a and 17b of collecting element 15. When surgical instrument 10 is removed from the surgical site, such as an intervertebral disc space, collecting element 15 facilitates removing the cut or curetted material from the surgical site.

From the foregoing detailed description and examples, it will be evident that modifications and variations can be made in the devices and methods of the invention without departing from the spirit or scope of the invention. Therefore, it is intended that all modifications and variations not departing from the spirit of the invention come within the scope of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A surgical instrument comprising:
 - a proximal end spaced along a shaft from a distal end and a longitudinal axis passing therethrough;
 - a working head at said distal end, said working head comprising:
 - a. a blade having a serpentine configuration and having a leading end and a trailing end spaced apart along said blade,
 - b. said blade having a first cutting surface extending from said leading end to said trailing end along a first edge of said blade and a second cutting surface extending from said leading end to said trailing end along a second edge of said blade, said first cutting surface and said second cutting surface arranged such that when said surgical instrument is rotated around said longitudinal axis in a first direction said first and second cutting surfaces are oriented for cutting and when said surgical instrument is rotated around said longitudinal axis in a second direction opposite to said first direction, said first and second cutting surfaces are not oriented for cutting; and
 - c. a collecting element at said leading end of said blade, said collecting element having a leading surface and a collecting surface to collect material cut by said blade.

2. The surgical instrument according to claim 1 wherein said first cutting edge is facing in a direction opposite said second cutting edge.
3. The surgical instrument according to claim 1 wherein said leading surface has a distal taper.
4. The surgical instrument according to claim 1 wherein said blade has a first diameter dimension when oriented in a first position and second diameter dimension, when said blade is oriented in a second position rotated 90 degrees around said longitudinal axis from said first position, said first diameter dimension greater than said second diameter dimension.
5. The surgical instrument according to claim 1 wherein said collecting element has a peripheral surface and said peripheral surface does not extend radially beyond said first and second cutting edges.
6. The surgical instrument according to claim 1 having a handle for rotating said instrument at said proximal end.
7. A surgical device for curetting an intervertebral disc between opposing first and second vertebrae, said surgical device comprising:
- a shaft have a proximal end and a distal end spaced apart along a longitudinal axis of said device;

- a blade extending from said distal end of said shaft, said blade having a leading end and a trailing end,
- said blade having a first concave surface facing a first direction and a first cutting edge and said blade having a second concave surface facing a second direction and a second cutting edge,
- said blade having a height dimension and a width dimension less than said height dimension, said first cutting edge at a first end of said height dimension and said second cutting edge at a second end of said height dimension;
- a diagonal dimension greater than said height dimension.

8. The surgical device according to claim 8 further comprising a collecting element at said leading end of said blade, said collecting element overlying a portion of said first concave surface and said second concave surface at said leading end of said blade.
9. The surgical device according to claim 7 wherein when said device is rotated in a first direction around said longitudinal axis said first and second cutting edges are oriented for cutting and when said device is rotated in a second direction around said longitudinal axis, opposite to said first direction said first and second cutting edges are not oriented for cutting.

10. The surgical device according to claim 8 wherein said collecting element has a tapered surface facing away from said leading end of said blade and a collecting surface facing toward said leading end of said blade.
11. The surgical device according to claim 7 wherein said first cutting edge is facing in a direction opposite said second cutting edge.
12. The surgical device according to claim 8 wherein a portion of a peripheral surface of said collecting element does not extend axially beyond a said first and second cutting edges.
13. The surgical device according to claim 7 having a handle for rotating said instrument at said proximal end.
14. A curette comprising:
- a shaft having a proximal end and a distal end spaced apart along a longitudinal axis of said curette;
 - a blade extending from said distal end of said shaft, said blade having a leading end and a trailing end,
 - said blade having an undulating configuration such that, a first side of said blade has a first concave region and a first convex region and a second side of said blade has a second concave region and a second convex region;

- said first side having a first cutting edge and said second side having a second cutting edge;
- a collecting element at said leading end of said blade, said collecting element overlying a portion of said first concave surface and said second concave surface.

15. The curette according to claim 14 wherein said first concave region and said second concave region face in opposite directions.
16. The curette according to claim 14 wherein said first concave region of said first side is adjacent said second convex region of said second side and said second concave region of said second side is adjacent said first concave region of said first side.
17. The curette according to claim 14 wherein when said curette is rotated in a first direction around said longitudinal axis said first and second cutting edges are oriented for cutting around said longitudinal axis and when said curette is rotated in a second direction around said longitudinal axis, opposite to said first direction, said first and second cutting edges are not oriented for cutting around said longitudinal axis.
18. The curette according to claim 17 wherein said first cutting edge is diametrically opposed to said second cutting edge.

19. The curette according to claim 18 wherein said collecting element has a tapered surface facing away from said distal end of said shaft and a collecting surface facing toward said distal end of said shaft.
20. The curette according to claim 14 wherein a portion of a peripheral surface of said collecting element does not extend beyond said first and second cutting edges.
21. The curette according to claim 14 having a handle for rotating said curette at said proximal end of said shaft.

Abstract of the Invention

An instrument for cutting and/or curetting during surgery is disclosed. The instruments of the invention are particularly advantageous for use in removing disc material from an intervertebral disc space. In a preferred embodiment, rotation of the
5 instrument around a longitudinal axis of the instrument provides for intermittently distracting vertebrae adjacent to the intervertebral disc space during rotation.

MERCHANT & GOULD P.C.

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: DISTRACTING AND CURETTING INSTRUMENT

The specification of which

- a. ☒ is attached hereto
b. ☐ was filed on _____ as application serial no. _____ and was amended on _____ (if applicable) (in the case of a PCT-filed application)
described and claimed in international no. _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (attached hereto).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

- a. ☒ no such applications have been filed.
b. ☐ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Albrecht, John W.	Reg. No. 40,481	Kowalchyk, Katherine M.	Reg. No. 36,848
Ali, M. Jeffer	Reg. No. 46,359	Lacy, Paul E.	Reg. No. 38,946
Anderson, Gregg I.	Reg. No. 28,828	Larson, James A.	Reg. No. 40,443
Batzli, Brian H.	Reg. No. 32,960	Leon, Andrew J.	Reg. No. P-46,869
Beard, John L.	Reg. No. 27,612	Liepa, Mara E.	Reg. No. 40,066
Berns, John M.	Reg. No. 43,496	Lindquist, Timothy A.	Reg. No. 40,701
Black, Bruce E.	Reg. No. 41,622	Lycke, Lawrence E.	Reg. No. 38,540
Branch, John W.	Reg. No. 41,633	McAuley, Steven A.	Reg. No. 46,084
Bremer, Dennis C.	Reg. No. 40,528	McDonald, Daniel W.	Reg. No. 32,044
Bruess, Steven C.	Reg. No. 34,130	McIntyre, Jr., William F.	Reg. No. 44,921
Byrne, Linda M.	Reg. No. 32,404	Mueller, Douglas P.	Reg. No. 30,300
Campbell, Keith	Reg. No. P-46,597	Pauly, Daniel M.	Reg. No. 40,123
Carlson, Alan G.	Reg. No. 25,959	Phillips, Bryan K.	Reg. No. P-46,990
Caspers, Philip P.	Reg. No. 33,227	Phillips, John B.	Reg. No. 37,206
Chiapetta, James R.	Reg. No. 39,634	Plunkett, Theodore	Reg. No. 37,209
Clifford, John A.	Reg. No. 30,247	Prendergast, Paul	Reg. No. 46,068
Daignault, Ronald A.	Reg. No. 25,968	Pytel, Melissa J.	Reg. No. 41,512
Daley, Dennis R.	Reg. No. 34,994	Qualey, Terry	Reg. No. 25,148
DalGLISH, Leslie E.	Reg. No. 40,579	Reich, John C.	Reg. No. 37,703
Daulton, Julie R.	Reg. No. 36,414	Reiland, Earl D.	Reg. No. 25,767
DeVries Smith, Katherine M.	Reg. No. 42,157	Schmaltz, David G.	Reg. No. 39,828
DiPietro, Mark J.	Reg. No. 28,707	Schuman, Mark D.	Reg. No. 31,197
Edell, Robert T.	Reg. No. 20,187	Schumann, Michael D.	Reg. No. 30,422
Epp Ryan, Sandra	Reg. No. 39,667	Scull, Timothy B.	Reg. No. 42,137
Glance, Robert J.	Reg. No. 40,620	Sebald, Gregory A.	Reg. No. 33,280
Goggin, Matthew J.	Reg. No. 44,125	Skoog, Mark T.	Reg. No. 40,178
Goffa, Charles E.	Reg. No. 26,896	Spellman, Steven J.	Reg. No. 45,124
Gorman, Alan G.	Reg. No. 38,472	Stoll-DeBell, Kirstin L.	Reg. No. 43,164
Gould, John D.	Reg. No. 18,223	Sumner, John P.	Reg. No. 29,114
Gregson, Richard	Reg. No. 41,804	Swenson, Erik G.	Reg. No. 45,147
Gresens, John J.	Reg. No. 33,112	Tellekson, David K.	Reg. No. 32,314
Hammer, Samuel A.	Reg. No. P-46,754	Trembath, Jon R.	Reg. No. 38,344
Hartre, Curtis B.	Reg. No. 29,165	Tuchman, Ido	Reg. No. 45,924
Harrison, Kevin C.	Reg. No. P-46,759	Underhill, Albert L.	Reg. No. 27,403
Hertzberg, Brett A.	Reg. No. 42,660	Vandenburgh, J. Derek	Reg. No. 32,179
Hillson, Randall A.	Reg. No. 31,838	Wahl, John R.	Reg. No. 33,044
Holzer, Jr., Richard J.	Reg. No. 42,668	Weaver, Karrie G.	Reg. No. 43,245
Johnston, Scott W.	Reg. No. 39,721	Welter, Paul A.	Reg. No. 20,890
Kadievitch, Natalie D.	Reg. No. 34,196	Whipps, Brian	Reg. No. 43,261
Karjeker, Shaukat	Reg. No. 34,049	Wickhem, J. Scot	Reg. No. 41,376
Kastelic, Joseph M.	Reg. No. 37,160	Williams, Douglas J.	Reg. No. 27,054
Kettelberger, Denise	Reg. No. 33,924	Witt, Jonelle	Reg. No. 41,980
Keys, Jeramie J.	Reg. No. 42,724	Wu, Tong	Reg. No. 43,361
Knearl, Homer L.	Reg. No. 21,197	Xu, Min S.	Reg. No. 39,536
Kowalchyk, Alan W.	Reg. No. 31,535	Zeuli, Anthony R.	Reg. No. 45,255

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant & Gould P.C. to the contrary.

Please direct all correspondence in this case to Merchant & Gould P.C. at the address indicated below:

Merchant & Gould P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903



I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

201	Full Name Of Inventor	Family Name Bagga	First Given Name Charanpreet	Second Given Name S.
	Residence & Citizenship	City Malvern	State or Foreign Country Pennsylvania	Country of Citizenship U.S.A.
	Post Office Address	Post Office Address 1083 King Road, Apt. HE111	City Malvern	State & Zip Code/Country PA 19355/U.S.A.
Signature of Inventor 201:				Date:
202	Full Name Of Inventor	Family Name Gray	First Given Name Eric	Second Given Name
	Residence & Citizenship	City Rockford	State or Foreign Country Minnesota	Country of Citizenship U.S.A.
	Post Office Address	Post Office Address 5720 Linda Lane	City Rockford	State & Zip Code/Country MN 55373/U.S.A.
Signature of Inventor 202:				Date:
203	Full Name Of Inventor	Family Name Regan	First Given Name John	Second Given Name E.
	Residence & Citizenship	City Plano	State or Foreign Country Texas	Country of Citizenship U.S.A.
	Post Office Address	Post Office Address 6300 W. Parker Road, Suite 100	City Plano	State & Zip Code/Country TX 75093/U.S.A.
Signature of Inventor 203:				Date:

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application:
- (2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.